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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,159	02/17/2004	Joseph DeMeo	KN P 0155	1270
42016 7590 06/29/2007 KENSEY NASH CORPORATION 735 PENNSYLVANIA AVENUE EXTON, PA 19341			EXAMINER CHEN, VIVIAN	
			ART UNIT 1773	PAPER NUMBER
			MAIL DATE 06/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/780,159

Applicant(s)

DEMEO ET AL.

Examiner

Vivian Chen

Art Unit

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 22-24, 28-31 and 33-41 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 23, 24 and 28-31, 33-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 5-21, 25-27, 32 have been cancelled by Applicant.

Claim Rejections - 35 USC § 112

1. The rejections under 35 U.S.C. 112, second paragraph, in the previous Office Action mailed 7/12/2006 has been withdrawn in view of Applicant's arguments filed 3/27/2007.

Claim Rejections - 35 USC § 103

2. Claims 1-4, 23-24, 28-31, 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over NAKAMURA ET AL (US 2003/0146541), in view of BURKHEAD ET AL (US 2001/0004693).

NAKAMURA ET AL '541 discloses a bone connecting device have a head and shank portion, wherein the shank is molecularly oriented and a head portion which is heated and reshaped to have a wider cross-section than the shank portion, wherein the shank portion has regions of lesser and greater orientation. The device comprises a bioabsorbable polymer (e.g., polylactic acid, polyglycolic acid, etc.) and optional reinforcing additives (e.g., alumina, zirconia, etc.). The device is subjected to additional processing to form additional structures (e.g., threads, etc.) (Figures 3-3C, 6B; paragraphs 0033, 0051, 0059) However, the reference fails to explicitly disclose a device in which the head has less orientation than the shank portion.

BURKHEAD ET AL discloses that it is well known in the art to have the region of reinforcement resulting from molecular orientation concentrated in the shank portion of a bone

Art Unit: 1773

fixing device, wherein the orientation elements optionally do not extend to the head portion (paragraph 0028), thus leaving the head portion of a bone fixing device with less reinforcement (i.e., molecular orientation) than the shank portion. (Figure 4A-4D) The reference also discloses that it is well known in the art to form tissue fixing devices with tapered or pointed shank portions in order to facilitate screwing or penetration into tissue.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make an implantable article having varying regions of self-reinforcement via molecular orientation in order to selectively increase the mechanical properties in high stress regions. The Examiner has reason to believe that the reheating and forming operations used in NAKMURA ET AL to reshape the head portion would at least partially disrupt the molecular orientation in the head portion, thereby producing a head portion with lesser molecular orientation than the shank portion. Regarding claims 23-24, 32-39, the recited steps are product-by-process limitations and is not further limiting in as so far as the structure of the product is concerned. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. ***The patentability of a product does not depend on its method of production.*** If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." [emphasis added] *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113. Once a product appearing substantially identical is found, the burden shifts to applicant to show a ***unobvious*** difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1993). See MPEP 2113. If the product in a product-by-

process claim is the same as or obvious from a product of the prior art, the product is unpatentable even though the prior product was made by a different process. The patentability of a product is based on the product itself, and is not dependent on its method of production.

Response to Arguments

3. Applicant's arguments filed 3/27/2007 have been fully considered but they are not persuasive.

(A) Applicant argues that NAKAMURA fails to teach the claimed invention because the reshaped head of the devices disclosed in the reference would not have molecular orientation substantially in the direction of the longitudinal axis of the device. However, the present claims do not require that the entire device (both head and shank) must have the same axis of molecular orientation (i.e., along the longitudinal direction). Therefore, the mere fact that the direction of the molecular orientation in the reshaped head portion of the NAKAMURA devices may differ from the direction of molecular orientation in other portions of the device is irrelevant.

(B) Applicant argues that BURKHEAD fails to disclose or suggest devices with differing degrees of orientation in different regions. Applicant further argues that the lines in Figures 4A-4D do not represent lines of molecular orientation and instead represent fibrous reinforcement. However, the Examiner is not persuaded. The reference clearly indicates that the lines in Figures 4A-4D are meant to represent "orientation and/or reinforcing elements" (paragraph 0028) -- the use of the term "and/or" clearly implies that the lines can be reasonably interpreted as representing lines (directions) of molecular orientation or lines of fibrous reinforcement.

(C) Applicant further argues that Figure 4D provides evidence that the lines only depict lines of fibrous reinforcement. As an initial matter, although Applicant contends that it is not possible to molecularly orient the polymer chains in a spiral pattern in two different directions, it is the Examiner's position that the apparently crossing lines can be reasonably interpreted by one of ordinary skill in the art as a somewhat crude attempt to depict a single-spiral pattern curving around and encircling the entire device (i.e., the spiraling lines in the front side of the device would be going in a direction perpendicular to the spiraling lines in the back side of the device and would hence appear to form 'crossing' lines). Such a position is further supported by the fact that such a single-spiral pattern is readily obtainable by simply applying a rotational stress during the orientation process.

(D) Applicant argues that BURKHEAD fails to disclose a device with different degrees of molecular orientation. However, since the reference explicitly shows the lines of molecular orientation extending through the head and shank (Figure 4E), thereby distinguishing it from devices in which the lines of molecular orientation do not extend through the entire device (Figure 4A), one of ordinary skill in the art would reasonable believe that the absence of explicitly drawn lines of molecular orientation would denote areas of reduced or less reinforcement (i.e., orientation).

(E) Applicant argues that BURKHEAD fails to teach the claimed invention because molecular orientation develops only when the polymer is in the glass transition range, and in a melt state. However, the stresses produced in extrusion and other forming processes are frequently sufficient to impose some degree of molecular orientation, even when the polymer is in a molten state, and this molecular orientation is retained when the polymer cools and

Art Unit: 1773

solidifies. Applicant's own specification indicates that molecular orientation can be obtained from articles formed from forming articles from molten polymers (specification, paragraph 0042, especially referencing U.S. Patent No. 4,968,317, which states that molecular orientation can be obtained from the processing and shaping of molten polymers, (line 30-43, col. 7)).

(F) Applicant argues that BURKHEAD fails to suggest the claimed invention because the BURKHEAD devices fail to have a longitudinal axis or an axis of symmetry. As an initial matter, the BURKHEAD devices are explicitly drawn and stated to have a "long axis" (paragraph 0028), which one of ordinary skill in the art as being equivalent to the claimed longitudinal axis. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an axis of symmetry) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(G) Applicant argues that NAKAMURA teaches away from the machining step recited in claim 24. However, while the reference discourages the use of cutting, the reference discloses that the device can be subjected to additional shaping operations to form threads and other structures. Since the term "machining" can be reasonably interpreted as applying not just to cutting operations, but also to any shaping or finishing process accomplished by a machine, the thread-forming process used in NAKAMURA encompasses the recited "machining" step.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1773

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivian Chen whose telephone number is (571) 272-1506. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney, can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

The General Information telephone number for Technology Center 1700 is (571) 272-1700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 7, 2006



Vivian Chen
Primary Examiner
Art Unit 1773